

**REMARKS**

Reconsideration of the application is respectfully requested. Claims 1-11 are pending and at issue.

**Anticipation Rejections**

Claims 1-3, 5-9, and 11 have been rejected under 35 U.S.C. § 102(a) as anticipated by Geusens et al., *J of Clin Densitometry*, 2001;4:389-394 (“Geusens”). According to the Examiner, Geusens discloses the case history of an 18-year old boy treated with intravenous pamidronate (a biphosphanate) for extreme back pain resulting from multiple vertebral fractures.

The rejection is respectfully traversed, and reconsideration is requested.

The present claims are directed to methods of treating “chronic spinal mechanical pain,” which is expressly defined in the specification at page 7, lines 15-16 as follows: “The term ‘chronic spinal mechanical pain’ is defined as any back pain lasting more than twelve weeks which is not caused by cancer, or an osteoporotic compression fracture.” Thus, the inventor acted as his own lexicographer by providing a precise definition of this claim term in the specification.

As the Examiner acknowledges, it is well established that claim terms should be interpreted in light of the specification, which courts have held to be “the single best guide to the meaning of a disputed term.” *See, Phillips v. AWH Corp.*, 415 F.3d 1303, 1315, 75 USPQ2d 1321 (Fed. Cir. 2005) (en banc). It is also well established that a patentee may “act as his own lexicographer,” defining claim terms to have meanings separate from their ordinary meanings. *See*, MPEP 2111.01(IV) (“An applicant is entitled to be his or her own lexicographer”); *see also, Abraxis Bioscience, Inc. v. Mayne Pharma Inc.*, 467 F.3d 1370, 1376 (Fed. Cir. 2006). MPEP §2111.01(IV) states: “Where an explicit definition is provided by the applicant for a term, that definition will

control interpretation of the term as it is used in the claim.” Consequently, both the MPEP and case law provide ample support for interpreting the present claims as being directed to methods of treating a type of pain that excludes cancer pain and osteoporotic compression fracture pain lasting more than 12 weeks. *See also*, MPEP §2111.01(II), which references *In re Weiss*, 989 F.2d 1202, 26 USPQ2d 1885 (Fed. Cir. 1993). In *Weiss*, the Federal Circuit emphasized that “we must look to the specification for the meaning ascribed to that term by the inventor.”

The Examiner cites *In re Morris*, 44 USPQ2d 1023 (Fed. Cir. 1993) for the proposition that the PTO is not required to interpret claims in the same manner as a court would in an infringement suit. Contrary to the Examiner, *Morris* does not hold that the PTO can ignore an express definition of a claim term in the specification. In fact, *Morris* states that:

[I]t would be unreasonable for the PTO to ignore any interpretive guidance afforded by the applicant’s written description ... [T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, *taking into account whatever enlightenment by way of definitions .. that may be afforded by the written description ...*

*Id.* at 1028 (emphasis added). Thus, in accordance with the case law and MPEP, the definition for the claim term “chronic spinal mechanical pain” provided in the specification can not be ignored. This definition excludes pain caused by osteoporotic compression fractures that lasts for more than 12 weeks. The Examiner acknowledges that “the patient described in Geusens has osteoporotic vertebral compression.” Thus, Geusens does not anticipate the pending claims because pain caused by this condition is expressly excluded. Accordingly, the Applicant respectfully requests that this rejection be withdrawn.

**Obviousness Rejections**

Claims 1, 4 and 10 have been rejected under 35 U.S.C. § 103(a) as obvious over Urban et al., *Society for Neuroscience Abstracts*, 2001;27(1):1326 (“Urban”) in view of U.S. Patent No. 6,676,970 (“Bader”). According to the Examiner, Urban discloses that zoledronate (a bisphosphonate) produces an anti-allodynic effect in rats, and Bader discloses parental zoledronate preparations. The Examiner contends that it would have been obvious to one of ordinary skill in the art to use intravenous zoledronate to treat pain based on these references.

The rejection is traversed, and reconsideration is respectfully requested.

As discussed above, the claim term “chronic spinal mechanical pain” is expressly defined in the present specification. Since claims are read in light of the specification, and because a patent applicant is entitled to act as his own lexicographer, this definition should not be ignored. Thus, “chronic spinal mechanical pain” excludes cancer pain that lasts for more than 12 weeks.

Urban is limited to the treatment of bone cancer-induced pain in rats using zoledronate. Because pain caused by cancer necessarily includes pain caused by bone cancer, the type of pain disclosed in Urban does not fall within the scope of the claim term “chronic spinal mechanical pain.” Bader does not cure the deficiencies of the primary reference because Bader discloses treating osteoporosis using bisphosphonates, but does not disclose using bisphosphonates to treat pain. Thus, no combination of Urban and Bader discloses or suggests treating “chronic spinal mechanical pain,” as this term is expressly defined by the inventors at page 7, lines 15-16 of the present specification.

In view of the foregoing, claims 1, 4 and 10 are not obvious over Urban and Bader; and Applicant respectfully requests that this rejection be withdrawn.

**Conclusion**

In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: September 25, 2007

Respectfully submitted,

By   
Paul M. Zagar

Registration No.: 52,392  
DARBY & DARBY P.C.  
P.O. Box 770  
Church Street Station  
New York, New York 10008-0770  
(212) 527-7700  
(212) 527-7701 (Fax)  
Attorneys/Agents For Applicant